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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/080,127	05/15/1998	ALEXANDER BLINKOVSKY	5253.200-US	9075

25907 7590 02/24/2003

NOVOZYMES BIOTECH, INC.
1445 DREW AVE
DAVIS, CA 95616

EXAMINER

TURNER, SHARON L

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/080,127

Applicant(s)

BLINKOVSKY ET AL.

Examiner

Sharon L. Turner

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 207-240 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 207-221 and 223-236 is/are allowed.
- 6) ☐ Claim(s) 237-240 ^{And 222} is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12-2-02 has been entered.
2. The amendment filed 10-17-02 has been entered into the record and has been fully considered. Claims 170-206 are canceled. New Claims 207-240 are pending.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 237-240 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification describes a single polypeptide sequence consisting of SEQ ID NO:2, which has aminopeptidase activity under the conditions recited in claim 237. However, claims 237-240 in contrast to claims 207-221 lack any structural limitations or guidance as to those structures which exhibit the required aminopeptidase functional

activity. Thus, the claims 237-240 encompass any structure which achieves amino peptidase activity under the conditions specified. Yet, the instant disclosure of a single polypeptide, that of SEQ ID NO:2 with the instantly disclosed specific activities, does not adequately describe the claimed genus drawn to a substantial variety of subgenera that are only described by function. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention". *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

An adequate written description, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a (product) DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the (product) DNA itself." *Id* at 1170, 25 USPQ2d at 1606."

Yet, in claims 237-240 there are no distinguishing structural features noted for the subgenera of functional variants or for functional fragments. The specification describes only a singular species (SEQ ID NO:2) which falls within the subgenus but fails to describe the structural features commonly possessed by it's members or an adequate number of species which distinguish the subgenus members from others.

Thus, as in *Regents of the University of California v Eli Lilly & Co*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), the naming of the type of material generally known to exist, in absence of knowledge as to what that material consists of, is not a description of that material. The artisan can not readily envision or discern those compounds which are members and thus the functional recitation alone fails to provide adequate written description to support the broad genus claimed.

5. Claims 237-240 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the aminopeptidase of SEQ ID NO:2, does not reasonably provide enablement for the generic recitation of any polypeptide providing aminopeptidase activity with the noted physiochemical properties noted in a)-d). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specifications disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without undue experimentation. The factors relevant to this discussion include the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims.

Claims 237-240 are drawn to any polypeptides or polypeptide fragments which provides for the physicochemical properties of elements a)-d) (aminopeptidase activity). Thus, the claims are akin to a single means claim, i.e., where a means recitation does not appear in combination with another recited element of means. Such is subject to an undue breadth rejection under 35 USC 112, first paragraph, see in particular MPEP 2164.08(a) and *In re Hyatt*, 708F.2d 712, 714, 715 (218 USPQ 195, 197) (Fed. Cir. 1983) where a single means claim which covered every conceivable means for

achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor. When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (polypeptide means) for achieving the stated property (aminopeptidase activity) while the specification discloses at most only those known to the inventor. In this case only SEQ ID NO:2 is disclosed as a peptide which exhibits the noted aminopeptidase activity under the specified physicochemical conditions.

Moreover, as to claims 237-240, the skilled artisan readily recognizes that protein chemistry is an unpredictable area of biotechnology. Proteins with replacement of single amino acid residues may lead to both structural and functional changes in biological activity and immunological recognition, see in particular Skolnick et al., Trends in Biotech., 18(1):34-39, 2000. For example, Choh et al., of record teaches a panel of amino acid substitutions which produce proteins that differ in native conformation, immunological recognition, binding and toxicity, thus exemplifying the importance of conserved structural components to both biological function and immunological recognition. Thus, the artisan could not a priori determine those sequences capable of sharing the functional constraints of the peptides claimed without undue experimentation.

Thus, in view of the lack of guidance, lack of examples, and lack of predictability associated with regard to producing and using the myriad of derivatives and fragments encompassed by the claims, one skilled in the art would be forced into further undue experimentation in order to determine those peptides which correlate to the recited functional characteristics of the claimed genus.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 222 is rejected under 35 U.S.C. 102(b) as being anticipated by Kundu et al., Applied Microbiology, April 1970, p. 598-603.

Claim 222 is directed to a method for producing the polypeptide of claim 207 comprising cultivating a microbial strain, which in its wild type form produces the polypeptide in a medium and under conditions suitable for the production of the polypeptide and recovering the polypeptide from the medium. Kundu teach cultivation of *Aspergillus oryzae* that is disclosed as the wild type organism producing the peptide of claim 207. The culture conditions are inherently effective for the production of the polypeptide as the conditions are suitable for the growth and propagation of the organism. Thus, the growth conditions are considered to be a medium and under conditions suitable for the production of the polypeptide produced by the organism, absent convincing factual evidence to the contrary. The polypeptide is considered to be suitably produced and recovered from the media in that the reference teaches the preparation of culture protein isolates from broth obtained by submerged fermentation, see in particular Materials and Methods, pp. 598, columns 1-2. The peptide is thus obtained from the culture isolates. Thus, the reference teachings anticipate the claimed invention.

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Status of Claims

8. Claims 207-221 and 223-236 are allowed.

Conclusion

9. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
February 20, 2003

Gary D. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600